

REMARKS

Applicants present this Amendment in conjunction with a Suggestion by Applicants for Interference pursuant to 37 C.F.R. § 41.202, wherein Applicants respectfully request that an interference be declared between the present application and U.S. Patent No. 6,869,605.

Status of the Claims

Upon entry of the present amendment, claims 195-207 will be pending in this application; these claims were added in the Amendment filed March 17, 2006. Claims 208-221 have been cancelled without prejudice or disclaimer herein. Applicants reserve the right to present claims to the cancelled subject matter at a later date in the present application or in a continuing application.

Request to Correct Inventorship Pursuant To 37 C.F.R. § 1.48(b)

Please correct the inventorship by deleting Craig A. Rosen, whose invention is no longer being claimed in the present application. Applicants have submitted the processing fee set forth in § 1.17(i) on the enclosed Processing Fee Transmittal Sheet.

Applicant Suggestion For Interference Pursuant To 37 C.F.R. § 41.202(a)

To facilitate consideration by the Examiner, the text of each of the subsections of 37 C.F.R. § 41.202(a) is set forth below as headings to each section providing the requisite information.

37 C.F.R. § 41.202(a)(1): Provide sufficient information to identify the application or patent with which the applicant seeks an interference

Under the provisions of 37 C.F.R. § 41.202(a)(1), Applicants seek to have an interference declared between the present application, U.S. Patent Application No. 09/589,288, and U.S. Patent 6,869,605 to Browning et al. ("the '605 Patent"), which is assigned on its face to Biogen Idec Ma Inc. (hereafter "Biogen"). The '605 Patent issued on March 22, 2005 from U.S. Patent Application No. 09/911,777, which was filed on July 24, 2001. A copy of the '605 Patent is attached as Appendix A.

37 C.F.R. § 41.202(a)(2): Identify all claims the applicant believes interfere, propose one or more counts, and show how the claims correspond to one or more counts

Applicants believe that claims 1-14 of the '605 Patent and claims 195-207 of the present application interfere.

Attached Appendix B sets forth a Proposed Count. The Proposed Count is also Claim 195 of the present application.

Claims of a patent or an application are presumed to correspond to a count if "the subject matter of the count, treated as prior art to the claim, would have anticipated or rendered obvious the subject matter of the claim." 37 C.F.R. § 41.207(b)(2).

Applicants believe that claims 1-14 of the '605 Patent should be designated as corresponding to the Proposed Count, as they would be anticipated by and/or obvious in view of the subject matter of the Proposed Count. The chart in Appendix C shows in detail why each of claims 1-14 of the '605 Patent should be designated as corresponding to the Proposed Count.

Applicants believe that claims 195-207 of the present application should be designated as corresponding to the Proposed Count, as they would be anticipated by and/or obvious in view of the subject matter of the Proposed Count. The chart in Appendix D shows in detail why each of claims 195-207 of the present application should be designated as corresponding to the Proposed Count.

37 C.F.R. § 41.202(a)(3): For each count, provide a claim chart comparing at least one claim of each party corresponding to the count and show why the claims interfere within the meaning of § 41.203(a)

To assist the Examiner, attached Appendix E is a chart that sets forth a side-by-side comparison of Claim 1 of the '605 Patent with Claim 195 of the present application (the Proposed Count). Appendix E also sets forth a side-by-side comparison of Claim 1 of the '605 Patent with Claim 196 of the present application.

As can be seen from Appendix E, the claims satisfy the two-way obviousness standard of 37 C.F.R. § 41.203(a). Accordingly, at least one claim of the present application and at least one claim of the '605 Patent recite interfering subject matter as required under 37 C.F.R. § 41.202(a)(3).

37 C.F.R. § 41.202(a)(4): Explain in detail why the applicant will prevail on priority

Applicants will prevail on priority because the present application is entitled to a priority benefit date of October 25, 1996, whereas the earliest possible priority date to which the '605 Patent may be entitled is January 25, 1999, *more than two years later*.

More particularly, the '605 Patent claims priority to International Application No. PCT/US00/01788, filed January 25, 2000, and through that application to U.S. Provisional Application No. 60/117,169, filed on January 25, 1999, and U.S. Provisional Application No. 60/143,228, filed on July 9, 1999. Accordingly, the earliest possible priority date to which the '605 Patent may be entitled with respect to the Proposed Count is January 25, 1999. The priority chain for the '605 Patent is presented graphically in Appendix F.

The present application was filed on June 8, 2000, and claims priority benefit to International Application No. PCT/US96/17957, filed October 25, 1996 through a chain of priority applications; the full priority chain for the present application is presented graphically in Appendix G. Excluding provisional applications, the present application claims priority as follows:

This application 09/589,288	Continuation of	09/507,968 (now U.S. 6,812,327)	02/22/2000
09/507,968	Continuation in part of	09/255,794 (now U.S. 6,716,576)	02/23/1999
09/255,794	Continuation in part of	09/005,874 (now U.S. 6,689,579)	01/12/1998
09/005,874	Continuation in part of	PCT/US96/17957	10/25/1996

Application Nos. 09/507,968 and 09/255,794 also claim priority to numerous provisional applications. *See* Appendix G. International Application No. PCT/US96/17957, and each application in the priority chain of the present application, describes and enables at least one embodiment within the scope of the Proposed Count as detailed in Appendices H and I below. Accordingly, because the present application is entitled to a priority date *more than two years* prior to the earliest possible priority date to which the '605 Patent may be entitled, Applicants will prevail on priority and should be designated as the senior party in the proposed interference.

In addition, prior to the earliest priority date to which the '605 Patent may be entitled, Applicants had actually inhibited B lymphocytes using an antibody that bound Neutrokine-

alpha as set forth in the Proposed Count. As discussed in the Declarations of Ms. Amy Orr and Dr. David Hilbert (attached as Appendices J and K), Ms. Orr conducted an experiment prior to August of 1998 in which she observed that an anti-Neutrokin-alpha monoclonal antibody inhibited Neutrokin-alpha-induced B lymphocyte proliferation. *See* Appendix J at paragraph 10; Appendix K at paragraph 6. In this experiment, B lymphocyte proliferation was induced by Neutrokin-alpha (referred to in Ms. Orr's laboratory notebook as "TL7"). *See* Appendix J, paragraph 10, second sentence, and the leftmost graph on page 114 of Exhibit B therein. When one of three monoclonal antibodies tested in this experiment was added at higher concentrations, the antibody inhibited this B lymphocyte proliferation. *See* Appendix J, paragraph 11, third sentence, and the rightmost graph on page 114 of Exhibit B therein (9B6; triangle line sloping downward). Although Ms. Orr's notebook uses the term "B-cell," this is interchangeable with the term "B lymphocyte" found in the claims, as noted by Ms. Orr in her Declaration at paragraph 4 (Appendix J), and as set forth in Appendix C at C-1, first bullet point.

Copies of partially redacted pages from Ms. Orr's laboratory notebook are attached to the Declarations, providing contemporaneous documentary evidence of this work. *See* Appendix J, Exhibits B and C. The Declaration of Dr. David Hilbert, Ms. Orr's supervisor at the time, further corroborates the performance of the relevant experiments. *See* Appendix K, paragraphs 4-6. As Dr. Hilbert discusses in his Declaration, Ms. Orr conducted the experiments discussed in her Declaration under his supervision, and he reviewed the results of these experiments with Ms. Orr when the results were obtained. *See* Appendix K, paragraph 6. Moreover, both Ms. Orr and Dr. Hilbert note that Dr. Hilbert and his manager Dr. Garotta reviewed Ms. Orr's notebook shortly after this experiment, and signed the notebook to confirm their review and comprehension of the results. *See* Appendix J at paragraph 10; Appendix K at paragraphs 7-8. Copies of the notebook pages signed by Drs. Hilbert and Garotta indicating this review are attached as Exhibit C to Ms. Orr's Declaration. *See* Appendix J.

Applicants note that neither the '605 Patent nor its earliest possible priority document, Application No. 60/117,169, shows that an antibody that binds Neutrokin-alpha (referred to therein as "BAFF") inhibits B lymphocyte proliferation (or any other B lymphocyte activity). Indeed, to overcome an enablement rejection during the prosecution of the application that led

to the '605 Patent, Biogen relied not upon its own work, but instead upon publications by Human Genome Sciences (HGS) and HGS' collaborators. More particularly, in the amendment Biogen filed on January 16, 2004 in the application that led to the '605 Patent, it relied upon abstracts by Wendy *et al.* and Furie *et al.* that described the inhibition of B lymphocytes by HGS' anti-Neutrokin- α antibody known as Lymphostat-B™ in preclinical animal studies and in Phase I human clinical trials. *See* Appendix L at page 4, first full paragraph; Wendy *et al.* and Furie *et al.* abstracts therein.

Thus, in addition to the fact that Applicants are entitled to a priority benefit date *more than two years* prior to the earliest possible priority date for the '605 Patent, Applicants will also prevail in this interference because scientists at HGS had inhibited the B lymphocyte proliferation induced by Neutrokin- α using an antibody that bound Neutrokin- α *more than five months* prior to the earliest possible priority date for the '605 Patent. Accordingly, Applicants should be designated as the senior party in the proposed interference and should prevail therein.

37 C.F.R. § 41.202(a)(5): If a claim has been added or amended to provoke an interference, provide a claim chart showing the written description for each claim in the applicant's specification

Claims 195-207 were added into the present application on March 17, 2006. The claims were not added for the specific purpose of provoking the interference, since claims encompassing interfering subject matter were already pending. Thus, because claims 195-207 were not added for the specific purpose of provoking an interference, Applicants do not believe that the claim chart described in 37 C.F.R. § 41.202(a)(5) is required. However, in order to facilitate review of the claims by the Examiner, Applicants submit herewith Appendix H, a claim chart which identifies exemplary written description support for claims 195-207 in the present application.

37 C.F.R. § 41.202(a)(6): For each constructive reduction to practice for which the applicant wishes to be accorded benefit, provide a chart showing where the disclosure provides a constructive reduction to practice within the scope of the interfering subject matter.

As detailed above, the present application was filed on June 8, 2000, and claims priority benefit to International Application No. PCT/US96/17957, filed October 25, 1996 through a chain of priority applications. Appendices H and I provide a chart showing where an exemplary constructive reduction to practice can be found for claims 195-207 in the present application and in each of the priority applications. Accordingly, as discussed above, the present application should be accorded benefit of the filing date of International Application No. PCT/US96/17957, October 25, 1996, and thus Applicants should be designated as the senior party in the interference.

CONCLUSION

Applicants respectfully request that an interference be declared employing the Proposed Count set forth in attached Appendix A, with claims 1-14 of the '605 Patent and claims 195-207 of the present application designated as corresponding to the count, and with Applicants designated as the senior party.

In the event that there are any questions concerning this paper, the Examiner is respectfully urged to telephone Applicants' undersigned representative so that prosecution of the application may be expedited.

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Respectfully submitted,

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